SUMMARY OF PRODUCT CHARACTERISTICS

(Vitamin E Capsules USP 400 IU)

1. Name of the Medicinal Product

Brand Name : Evictal 400 Capsules

Generic Name: Vitamin E Capsules USP 400 IU

2.Qualitative and Quantitative Composition

Each soft gelatin capsule contains:

Vitamin E Acetate BP ……. 400 IU

3. Pharmaceutical Form

Soft gelatin capsules

Physical Description: Green coloured transparent oval shaped soft gelatin Capsules containing oily liquid .

4. Clinical Particulars

4.1 Therapeutic Indications

Evictal 400 is indicated as a supplement in conditions where a deficiency of vitamin E exists.

Diagnosis of vitamin E deficiency should be documented and based on

-measuring the plasma a-tocopherol level(Level < < 5µg/mL or <11.6 µmol/L indicate vitamin E deficiency and /or

- ratio of plasma α-tocopherol to plasma lipid level (in adults; < 0.8 mg/g total lipid).

4.2 Posology and Method of Administration

Posology

Dosage should be adjusted to the type of disorder and the patient's clinical conditions

One unit (IU) of vitamin E equals the biologic activity of 1 mg of all rac-α-tocopheryl acetate (dl-α-tocopheryl acetate).

Adults (including the elderly):-ataxia with vitamin E deficiency (AVED): 800 mgdaily,divided into two doses During vitamin E therapy, plasma vitamin E concentration should be checked at regular intervals.

Pediatrics Population

This medicine should not be used in children.

Patients with renal impairment and Hepatic impairment

There is no dose adjustment necessary in patients with renal impairment and hepatic impairment.

Method of Administration

For oral Administration.

Take this medicine during or after a meal.

4.3 Contraindications

Use in patients with known hypersensitivity to Vitamin E.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

4.4 Special Warnings and Special Precautions for Use

Vitamin E has been reported to increase the risk of thrombosis in patients predisposed to this condition, including patients taking oestrogens.

Vitamin E should be used with caution in pregnancy especially during the first trimester. No information is available on excretion of vitamin in breast milk, therefore it is advisable not to use during lactation.

4.5 Interaction with other Medicinal Products and other forms of Interaction

Vitamin E may increase the risk of thrombosis in patients taking oestrogens.

4.6 Pregnancy and Lactation

There is no evidence of the safety of high doses of vitamin E in pregnancy nor is there evidence from animal work that it is free from hazard, therefore do not use in pregnancy especially in the first trimester. No information is available on excretion in breast milk, therefore it is advisable not to use during lactation.

4.7 Effects on Ability to Drive and Use Machines

None known

4.8 Undesirable Effects

Diarrhoea and abdominal pain may occur with doses greater than 1g daily.

4.9 Symptoms and Treatment of Overdose

Transient gastro-intestinal disturbances have been reported with doses greater than 1g daily and where necessary, general supportive measures should be employed.

Please tell your doctor or pharmacist as soon as possible when you taken more than the recommended dose.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Vitamin E

ATC code: A11HA03

The exact role of vitamin E in the animal organism has not yet been established. Vitamin E is known to exert an important physiological function as an antioxidant for fats, with a sparing action on vitamin A, carotenoids and on unsaturated fatty acids. Other work has demonstrated that vitamin E is connected with the maintenance of certain factors essential for the normal metabolic cycle.

5.2 Pharmacokinetic Properties

Vitamin E is absorbed from the gastrointestinal tract. Most of the vitamin appears in the lymph and is then widely distributed to all tissues. Most of the dose is slowly excreted in the bile and the remainder is eliminated in the urine as glucuronides of tocopheronic acid or other metabolites.

5.3 Preclinical Safety Data

None known

6. Pharmaceutical Particulars

6.1 List of Excipients

Gelatin Mass Preparation

- Gelatin BP
- Glycerin BP
- Sorbitol Solution (70%) (Non Crystallising) BP
- Methyl Hydroxybenzoate BP
- Propyl Hydroxybenzoate BP
- Color Apple Green FCF Supra IH
- Purified water BP

Medicament Preparation

- All-rac-alfa Tocopheryl Acetate (Active Ingredients)

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

24 Months

6.4 Special Precautions for Storage

Store in a dry place below 30^0 C, Do not Freeze. Protect from light

Keep all medicines out of reach of children.

6.5 Primary Pack / Description of Nature and Content of container

Aluminum and PVC Blister 3 x10 Capsules

6.6 Instructions for Use and Handling

None

7. MARKETING AUTHORISATION HOLDER

Name : INDCHEMIE HEALTH SPECIALITIES PVT.LTD.

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8. MARKETING AUTHORIZATION NUMBER

9. DATE OF FIRST <REGISTRATION> / RENEWAL OF THE <REGISTRATION>

10. DATE OF REVISION OF THE TEXT